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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,433	06/07/2005	Martin Schulte	MERCK-3589	9936

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EXAMINER
RAJAN, KAI

ART UNIT	PAPER NUMBER
3769	

NOTIFICATION DATE	DELIVERY MODE
04/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2010*.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 9 – 11, 14 – 18, and 21 - 23* is/are pending in the application.

    4a) Of the above claim(s) *22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 9 – 11, 14 – 18, and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the reply filed January 27, 2010.

Election/Restrictions

Applicant's traversal of the election be original presentation applied to claims 22 and 23 is not found persuasive. First, the Examiner agrees that the term "network" would provide clarification of the claims' meaning over "practice management system," and overcome 112, 2nd paragraph issues. Paragraph 0051 of the specification states that the ALEX system may be networkable, or "stand alone, i.e. can be operated without connection to practice management systems." Since a standalone system is described as the alternative to a networked system, the standalone system is not networked. Turning to the claims, claims 1 and 11 both disclose patient data stored in anonymized form in a storage device. Such storage device is described on pages 5 and 14 of the specification as either a central location or a database at a server. As such, the Examiner has interpreted the system throughout the prosecution as a networked system with at least a networked storage device. Therefore, the election by original presentation of a networked system is proper, and claims 22 and 23 remain withdrawn.

Response to Arguments

Applicant's arguments have been considered and are persuasive, therefore the finality of the previous action has been withdrawn. The arguments are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 11 are rejected, since the addition of a "computer readable medium" to the claims has not cured the deficiencies of claims 1 and 11. In particular, "computer readable medium" is not explicitly defined in the written disclosure as a tangible medium. Under its broadest reasonable interpretation, "computer readable medium" encompasses transitory mediums including signals and carrier waves, which are not tangible and therefore non-statutory. Furthermore, regarding claim 1, storing point values in a computer readable medium is insignificant extra-solution activity, and the essential steps of the method are not sufficiently tied to the apparatus performing the steps. Claims 9, 10, 14 - 18, and 21 are rejected based on their dependency from claims 1 and 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 9 – 11, 14 – 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iliff U.S. Patent No. 5,868,669, in view of Skardon U.S. Patent No. 6,288,646 B1, further in view of Fey et al. U.S. PGPub No. 2002/0038227 ("Fey").

Iliff discloses a method for recording and analyzing diseases and their causes and for establishing appropriate therapy proposals comprising:

a) preparing at least one set of anamnesis questions, wherein the anamnesis questions include questions relating to the time and/or cause of the occurrence, the severity of, symptoms of an allergic disease and the environmental exposure of a patient, and storing this set in a data memory in a computer-readable media (Iliff column 35 lines 51 – 57, column 36 lines 11 – 49, column 39 lines 1 – 11 questions are presented to the user to collect information about medical history and identifying causes, symptoms, and the severity of symptoms),

b) preparing a set of data relating to the causes of diseases, and storing this set in a data memory in a computer-readable media, wherein the data is continuously revised and extended (Iliff column 12 lines 24 – 60, column 35 lines 25 – 64 question sets used to collect medical history data and to narrow diagnoses are retrieved and presented to the user based in part on the user's possible condition. The question sets are continuously revised with new questions as new diseases are discovered),

c) providing a computer program which selects and presents anamnesis questions according to a predetermined set of rules (Iliff column 12 lines 24 – 60, column 35 lines 25 – 64, column 36 lines 1 – 49 question sets to collect medical history data and to narrow diagnoses are retrieved and presented to the user based in part on the user's possible condition.),

d) recording the answers to the anamnesis questions in a computer-readable media, wherein within the framework of the anamnesis questions preliminary information is recorded which includes at least the age and gender of a patient and optionally one or more affected organs and/or other diagnosed illnesses, and wherein the answers are at least partly

predetermined in discrete selection steps (Iliff column 30 lines 3 – 30, column 35 lines 51 – 57,

column 36 lines 11 – 49, column 39 lines 1 – 11 answers to questions are recorded in a patient

medical history file which includes age and gender data, as well as information identifying the

anatomic system, causes of illness, and severity of symptoms experienced),

Regarding steps (e), (f), and (g), Iliff discloses scoring responses to questions and

summing the scores until thresholds are reached in the diagnosis process (Iliff column 5 lines 36

– 57, column 39 lines 6 – 67, column 40 lines 1 – 61). The thresholds are set to identify different

causes of medical issues, which are diagnoses, and the determined causes are ranked based on

scores and exceeded thresholds (Iliff column 39 lines 5 – 67, column 40 lines 1 – 61). While

Iliff positively discloses scoring question responses and using the scores for diagnoses, it is

submitted by the Examiner that numerous equivalent diagnosis methods are known aside from

scoring responses to questions. The use of a scoring system is an obvious variant of other

methods such as decision tree algorithms that use responses to questions or entered data to filter

through possible diagnoses and arrive at the most probable diagnosis.

g) creating a set of possible diagnoses using the criterion of whether the total point values

for specific groups of answers and/or the entire anamnesis exceed a predeterminable threshold

value and preparing a proposal for the allergens to be tested to further narrow down the diagnosis

(Regarding (g) through (k) Iliff column 24 lines 29 – 42, column 36 lines 11 – 33, column 39

lines 5 – 67, column 40 lines 1 – 61, column 41 lines 11 – 67, column 42 lines 1 – 48 probable

causes and diagnoses are identified by the scores and exceeded thresholds. The system further

narrows its list of probable causes including allergies by asking additional questions which

comprise additional tests. Probable causes and conditions are ranked by the computer program

based on scores of questions, which comprises a preparation and display of diagnosis proposals.

Furthermore, the system prepares and outputs suggestions to the patient including additional tests

to perform to confirm the probable diagnosis, suggestion medical actions to be taken such as

treatment or visits to a physician, and stores this data with other patient data in the system

database).

Iliff discloses a computerized, knowledge based medical diagnostic and treatment system.

The system diagnoses and provides advice to patients based on collected medical history data

regarding symptoms, diseases, and medication data. Questions regarding different medical

conditions and symptoms are presented to the user, and answers are scored for diagnostic

purposes. The system is not limited in scope to any particular disease, and is even adaptive to

newly discovered diseases (Iliff column 12 lines 24 – 35). Allergies are disclosed in and

discussed throughout the reference as a disease monitored within the scope of the invention (Iliff

column 36 lines 11 – 33, column 47 lines 6 – 15). Iliff fails to explicitly disclose collecting

medical history data regarding allergens and does not discuss examples of using the invention for

patients with allergies. However, Skardon a reference in an analogous art of patient data

collection and diagnosis discloses collecting allergen data in conjunction with medical history

data, and providing diagnosis and advice information to the patient (see at least Skardon

"Summary of the Invention"). It would have been obvious to one of ordinary skill in the art at

the time of the invention to combine the teachings of Skardon with the invention of Iliff to

diagnose and tend to patients with allergic diseases, since the invention of Iliff is generally

intended to address diseases, and Skardon explicitly identifies allergen - related diseases as

prominent medical issues to be addressed (Skardon column 1 lines 10 – 24). Therefore, it is

obvious to use the invention of Iliff to collect medical history data including allergens, diagnose,

and provide treatment information and advice for patients with allergic diseases.

Iliff and Skardon disclose a patient database that stores data for multiple patients. Iliff and Skardon fail to disclose *data stored in anonymized form*. However, Fey a reference in an analogous art of health screening and diagnosis discloses a networked medical database system that stores records in an anonymous manner (Fey paragraphs 0065, 0094). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Iliff and Skardon with the anonymized medical records of Fey, since Fey states that storing records in an anonymous manner protects personal information from becoming public, and the user can benefit from medical advancements without endangering privacy (Fey paragraphs 0065).

Furthermore, Iliff and Skardon fail to disclose *selecting comparable data based on a user's medical history*. However, Fey a reference in an analogous art of health screening and diagnosis discloses a networked health screening system that queries a database of a population for similar trends and results (Fey paragraphs 0025, 0065, 0094). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the diagnosis system of Iliff and Skardon with the population database of Fey, since Fey states that having more current information available to the medical community provides leaps forward in preventative care and early intervention, and the population information can help better develop risk assessments (Fey paragraph 0094).

9. A method according to Claim 1, wherein step g) includes the comparison of the obtained set of answers with other sets of answers which have been obtained from earlier anamneses (Fey paragraphs 0025, 0094).

10. A method according to Claim 1, wherein contraindications are recorded prior to the preparing of therapy proposals (Iliff column 13 lines 14 – 29, column 25 lines 1 – 30 data regarding medication history and experiences are collected and recorded in the medical history file).

18. A method according to Claim 1, wherein contraindications are recorded prior to the preparing of therapy proposals within the framework of d) (Iliff column 13 lines 14 – 29, column 25 lines 1 – 30 data regarding medication history and experiences are collected and recorded in the medical history file).

21. A method according to Claim 1, wherein the computer program has a scale valuation and combination of the scale valuations of individual answers for the analysis of the recorded data (Iliff column 39 lines 6 – 67, column 40 lines 1 – 61).

Claims 11, and 14 – 17 are rejected by the system performing the method of Iliff in view of Fey (see rejection above for citations to prior art).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Altman et al. U.S. Patent No. 5,572,421, cited by Applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/   /Henry M. Johnson, III/
Examiner, Art Unit 3769   Supervisory Patent Examiner, Art Unit
                                                3769

April 22, 2010